DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our STN: BL 103694/5004

SEP 18 2002

Genetics Institute, Incorporated
c/o Tracy D. Rockney
Wyeth Pharmaceuticals
150 North Radnor-Chester Road
St. Davids, PA 19087

Dear Ms. Rockney:

Your request to supplement your biologics license application for Oprelvekin to revise the physician package insert to state that a safe and effective dose has not been established for pediatric patients and to add important new safety information has been approved.

We acknowledge your written commitment as described in your facsimile (to be followed in official hard copy) of September 17, 2002, to submit a revised patient package insert to STN 103694/5014 by September 27, 2002.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 2567. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

This information will be included in your biologics license application file.

Sincerely yours,

Patricia Keegan for Dr. Weiss

Karen D. Weiss, M.D.
Director
Division of Clinical Trial Design
and Analysis
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research